K122783

510(k) SUMMARY (as required by 21 CFR 807.92)

Plasmafit Pro Acetabular Cup System and Vitelene Insert

October 30, 2013

COMPANY:
Aesculap Implant Systems, LLC
3773 Corporate Parkway
Center Valley, PA 18034

Establishment Registration Number: 3005673311

OCT 3 0 2013

CONTACT:
Julie Tom Wing
610-984-9147 (phone)
610-791-6882 (fax)
julie.tomwing@aesculap.com

TRADE NAME:

Plasmafit Pro Acetabular Cup System and Vitelene Insert

COMMON NAME:

Acetabular Cup and Insert

CLASSIFICATION NAME(s):
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis;

Hip joint metal/polymer semi-constrained cemented prosthesis;

Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis;

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

REGULATION NUMBER: 888.3358; 888.3350; 888.3360; 888.3353

CLASSIFICATION PRODUCT CODE(S): OQG

SUBSEQUENT PRODUCT CODE(S): LPH; JDI; OQH; LWJ; LZO; OQI

DEVICE DESCRIPTION

Aesculap Plasmafit Pro Acetabular Cup System and Vitelene Insert is a modular hip prostheses system intended to be used in conjunction with a prosthetic femoral head and hip stem in total hip arthroplasty.

Aesculap Plasmafit Pro consists of a cementless titanium acetabular cup, a highly crosslinked (β-75 kGy) ultra-high molecular weight polyethylene (UHMW-PE) vitamin E insert, 40mm Biolox® delta, 40mm ISODUR® heads and optional titanium screws.

The hemispherical titanium cup with a slightly flattened dome is coated with a titanium plasma spray on the outer surface which aims to provide a high level of primary stability with its rough finish. Plasmafit Pro cups are available in three (3) similar designs only varying in the number of holes (0, 3, 5/7) around the apex. The number of holes are adapted for optional anchoring 6.5mm diameter titanium alloy screws that may be used to ensure primary stability. Plasmafit Pro anchoring screws are an option available separately in sizes 16mm to 68mm lengths.

Vitelene is designed with a taper-fit to the interior surface of Plasmfit Pro cups. The vitamin E insert has been shown to be more resistant to oxidation than conventional UHMWPE. Characterization of the oxidation indices of aged (ASTM F2003) and un-aged Vitelene measured according to ISO 5834-4 did not decrease . Further, Vitelene remains resistant to oxidation after 5 million cycles of wear as demonstrated in testing performed in accordance to ISO 14242.

Plasmafit Pro cups are available in sizes ranging from 40mm – 70mm.

Plasmafit Pro Acetabular Cup System and Vitelene insert may be used with Aesculap Biolox® delta and ISODUR® (CoCrMo) 40mm ball heads along with the following cleared compatible components: Aesculap Hip Implant Systems Excia, Metha, Prevision, and Unisyn and cleared Aesculap femoral heads: Biolox® Option, Biolox® Forte, Biolox® Delta, and CoCrMo to offer several interoperative implant options taking into consideration different patient bone conditions.

PURPOSE FOR PREMARKET NOTIFICATION

The purpose for this submission is to gain marketing clearance for Aesculap Implant Systems Plasmafit Pro Acetabular Cup, Vitelene insert, optional titanium screws and 40mm Biolox® and 40mm ISODUR® femoral heads.

INDICATIONS FOR USE

The Plasmafit Pro Acetabular Cup System and Vitelene Insert are intended for use with existing Aesculap femoral heads and femoral stems to replace the hip joint.

The devices are intended for:

- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral ephiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

Plasmafit Pro Acetabular Cup System and Vitelene Insert are intended for cementless applications.

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC believes that the Plasmafit Pro Acetabular Cup System and Vitelene insert is substantially equivalent to:

- Excia Total Hip System (Aesculap - K042344)
- Excia Total Hip System (Aesculap - K061699)
- EXp Acetabular Shell Insert (StelKast, Inc. - K094035)
- Mectacer 40mm Biolox Delta Heads (K11215)
- Mpact 40mm Ball Heads (K103721)

TECHNOLOGICAL CHARACTERISTICS (compared to Predicate(s))

Aesculap Implant Systems Plasmafit Pro Acetabular Cup and Vitelene Insert is an acetabular cup system that is substantially equivalent to the predicate devices previously cleared by FDA. The subject device is shown to be substantially equivalent and has the same technological characteristics to predicate devices through comparison of indications for use, design, material composition, function and range of sizes.

PERFORMANCE DATA

As recommended by the FDA Guidance for Industry and FDA Staff - Non-clinical testing was performed to demonstrate that Plasmafit Pro Acetabular Cup and Vitelene Insert System is substantially equivalent to other predicate devices. In addition, testing was performed where applicable per FDA Guidance documents:

- "Testing of Metallic Plasma Sprayed Coating on Orthopedic Implant to Support Reconsideration of Postmarket Surveillance";
- "Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement"
- "Testing Non-Articulation, 'Mechanically Locked,' Modular Implant Components

Testing demonstrated that the Plasmafit Pro Acetabular Cup System and Vitelene Insert is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 30, 2013

Aesculap Implant Systems, Incorporated
Ms. Julie Tom Wing
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K122783
Trade/Device Name: Plasmafit Pro Acetabular Cup System and Vitelene Insert
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: OQG, LPH, JDI, OQH, LWJ, LZO, OQI
Date: October 24, 2013
Receiver: October 28, 2013

Dear Ms. Julie Tom Wing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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A. INDICATIONS FOR USE STATEMENT

510(k) Number: K122783

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Prescription Use __X__ and/or Over-the-Counter Use_____(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices